NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INDUSTRIENS PENSIONSFORSIKRING A/S, Individually and On Behalf of All Others Similarly Situated Plaintiff, v. BECTON, DICKINSON AND COMPANY, VINCENT A. FORLENZA, THOMAS E. POLEN, and CHRISTOPHER R. REIDY, Defendants.	Case No. 2:20-cv-02155-SRC-CLW **OPINION**

CHESLER, District Judge

This securities fraud action seeks to recover losses allegedly sustained as a result of the failure of Becton, Dickinson and Company ("BD" or the "Company") to disclose certain deficiencies in one of its flagship medical products and the related regulatory action that would be required by those deficiencies. Lead Plaintiff Industriens Pensionsforsikring ("Plaintiff") brings this putative class action pursuant to the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4(a)(3)(B), on behalf of all persons or entities who purchased or otherwise acquired the common stock of BD between November 5, 2019, and February 5, 2020, inclusive (the "Class Period"). The Second Amended Complaint (the "SAC") asserts three causes of action: (1) a claim for violation of Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a, et seq. (the "Exchange Act") against BD and individuals Vincent Forlenza, Thomas Polen and Christopher Reidy (the "Individual Defendants" and, collectively with BD,

"Defendants")[1], (2) a control person claim pursuant to Section 20(a) of the Exchange Act against the Individual Defendants, and (3) an insider trading claim pursuant to Sections 10(b) and 20A of the Exchange Act against Defendants Forlenza and Polen.

In brief, Plaintiff contends that Defendants committed fraud when they failed to disclose that BD's Alaris infusion pumps suffered from various product defects, and that BD had over a five-year period made numerous changes to Alaris products without approval by the Food and Drug Administration (the "FDA") through the FDA's 510(k) application process while simultaneously recognizing internally that such 510(k) clearance was required. On this basis, the claimed securities fraud violation consists of allegedly misleading statements concerning the Alaris devices, the Company's regulatory compliance program, and the Company's financial guidance.

Presently before the Court is the motion filed by BD and the Individual Defendants to dismiss the SAC. Plaintiff opposes the motion. The Court has considered the parties' written submissions and, for the reasons that follow, will grant Defendants' motion to dismiss the SAC. Plaintiff hereby is granted leave to amend the complaint within 45 days of the entry of the Order to issue with this Opinion.

---

[1] Forlenza served as BD's Chief Executive Officer from October 2011 until January 2020 and at all relevant times also served as the Chairman of the Board of Directors. (SAC ¶ 29.) Polen served as BD's President since 2017 and from October 2014 to April 2017 he was the Executive Vice President and President of the BD Medical Segment. (SAC ¶ 30.) Polen also served as BD's Chief Operating Officer until January 2020, at which time he replaced Forlenza as CEO. (SAC ¶ 30.) Reidy served as BD's Executive Vice President, Chief Financial Officer, and Chief Administrative Officer since July 2013. (SAC ¶ 31.)

In addition to the Individual Defendants, Plaintiff alleges that certain of the statements at issue were made by John Gallagher, BD's then-Senior Vice President, -Treasurer, and -CFO of BD. (SAC ¶ 187.) For purposes of this analysis, statements concerning the Individual Defendants, generally, are intended to include CFO Gallagher unless otherwise noted.

I. BACKGROUND[2]

BD is a New Jersey-based medical technology company engaged primarily in manufacturing and selling medical devices, instrument systems, and reagents. (SAC ¶ 26.) BD's business is comprised of three business segments: BD Medical, BD Life Sciences, and BD Interventional. (SAC ¶ 27.) BD's Medication Management Solutions ("MMS") unit, which is housed within BD Medical, focuses primarily on infusion systems and dispensing technologies. (SAC ¶ 28.)

In 2015, BD acquired CareFusion Corp. ("CareFusion"), a San Diego-based medical technology company giving BD the right to manufacture, market, and distribute the Alaris infusion pump system and associated technologies. (SAC ¶¶ 78–79.) Infusion pumps are electronic, external medical devices that deliver fluids into a patient's body in a controlled manner and commonly are used to deliver blood, nutrients, or medications such as insulin, antibiotics, chemotherapy drugs, and pain relievers. (SAC ¶ 33.) These pumps consist of both hardware and software in their operation and are often paired with related devices and software platforms in comprehensive "medication management" systems. (SAC ¶¶ 34–35.) Due to their use in administering critical fluids to high-risk patients, the infusion pumps' consistent and accurate operation, along with sufficient training and appropriate use, is important to avoid potential injury, including death, to the patients using them. (SAC ¶ 36.)

A. Federal Regulation of Infusion Pumps

Because of its use in medical processes, infusion pumps are subject to regulation by the Food and Drug Administration (the "FDA") pursuant to the Food, Drug, and Cosmetic Act (the

[2] The background sets forth facts alleged in the SAC and contained in documents attached to or referenced in the SAC. The facts are taken as true for purposes of this motion to dismiss only.

"FD&C Act"), as amended by the Medical Device Amendments of 1976. (SAC ¶ 37.) The FDA classifies infusion pumps as "Class II" medical devices (SAC ¶ 38), as they possess the potential for dangerousness and "general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness." 21 U.S.C. § 360c(a)(1)(B).

To regulate these devices, the FDA requires manufacturers to establish quality control mechanisms ensuring that the devices meet current good manufacturing practice standards. 21 C.F.R. § 820.30. For Class II devices, a manufacturer's quality control systems must involve documenting and maintaining records relating to software or other design changes, including any analysis, testing, and decisions associated with software changes to its medical devices.[3] The failure to comply with regulatory standards may result in the issuance of a Form 483—used by the FDA to notify manufacturers of significant objectionable conditions or violations discovered during inspections—a warning letter, fines, seizure or recall of products, or product bans. (SAC ¶ 43.) The FDA may also seek a court order enjoining individuals and corporations from continuing to violate the FD&C Act or recommend criminal prosecution by the Justice Department. (SAC ¶ 43.)

As Class II medical devices, infusion pumps must be approved for distribution and monitored with respect to device changes through the FDA's Premarket Notification 510(k) Program. (SAC ¶ 45.) This program requires that a manufacturer of a Class II device submit to the FDA a 510(k) application when: (i) introducing a device into commercial distribution for the

[3] See 21 C.F.R. § 820.30 (manufacturer must establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met); 21 C.F.R. § 820.70 (manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure); 21 C.F.R. § 820.181 (manufacturer must document changes and approvals in the device master record); see also Deciding When to Submit a 510(k) for a Software Change to an Existing Device, U.S. Food & Drug Admin., Oct. 25, 2017.

first time; or (ii) introducing "[a] change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process" or "[a] major change or modification in the intended use of the device." 21 C.F.R. § 807.81(a). To obtain approval through the 510(k) process, the manufacturer must demonstrate that its device is at least as safe and effective as, or "substantially equivalent" to, an existing device that has already been approved. Id. The manufacturer must submit a 510(k) application at least ninety days before it intends to begin marketing the device. See 42 Fed. Reg. 42520, 42522 (Aug. 23, 1977) ("[T]he burden is on the manufacturer to determine whether a premarket notification should be submitted for a change or modification in a device. The Commissioner believes that the manufacturer is the person best qualified to make this determination.").

On October 25, 2017, the FDA released guidance regarding when a 510(k) application and FDA clearance are required in a document entitled Deciding When to Submit a 510(k) for a Software Change to an Existing Device (the "FDA 510(k) Guidance" or the "Guidance").[4] Such changes include where: (i) "the change introduce[s] a new risk or modif[ies] an existing risk that could result in significant harm and that is not effectively mitigated in the most recently cleared device"; (ii) "the change create[s] or necessitate[s] a new risk control measure or a modification of an existing risk control measure for a hazardous situation that could result in significant harm"; or (iii) "the software change could significantly affect clinical functionality or performance specifications that are directly associated with the intended use of the device." FDA 510(k) Guidance at 12–13. The obligation to submit a 510(k) application may arise where the collective impact of discrete software changes—which individually may fail to meet the standard—meets

[4] See Decl. of James Smith III, Ex. B.

the standards set forth in the Guidance. FDA 510(k) Guidance at 7–8. The Guidance also identifies certain software changes that do not require 510(k) approval, including changes "made solely to strengthen cybersecurity" or "that only restores the device to the specifications of the most recently cleared device." FDA 510(k) Guidance at 11.

Manufacturers are further required to report certain device-related adverse events and product problems to the FDA, including when they become aware that: (i) any of their devices may have caused or contributed to a death or serious injury; or (ii) their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. 21 C.F.R. § 803. The company may then do one of three things: (i) propose a correction; (ii) remove the product from the stream of commerce; or (iii) voluntarily recall the product. Id.[5] In some circumstances, corrections related to voluntary recalls may be implemented while the device continues to be marketed and remains in use and available in the field. (SAC ¶ 55.)

B. The Alaris Infusion Pump

Alaris first received 510(k) clearance over 25 years ago, in 1995. (SAC ¶ 87.) Since then, it has been manufactured and marketed by a variety of entities, including IMED Corp., Cardinal Health, CareFusion, and BD. (SAC ¶¶ 87–89.)

Alaris has been the subject of a number of safety concerns over the years. In August 2006, Cardinal Health, which then manufactured Alaris, initiated a Class I recall of certain Alaris models due to the potential for over-infusion caused by a software issue. (SAC ¶ 70.) As part of the recall,

[5] The FDA classifies recalls based on the degree of risk associated with the defective device. A Class I designation is the most serious and indicates that there is a reasonable chance that a defective product will cause serious health problems or death. A Class II designation indicates that a product may cause a temporary or reversible health problem, or that there is a slight chance that it will cause serious health problems or death. A Class III designation indicates the defective product is not likely to cause any health problem or injury. (SAC ¶ 57.)

letters and warning labels were sent to the customers of approximately 140,000 pumps. (SAC ¶ 68.) Shortly after the announcement of the recall, the U.S. Attorney for the Southern District of California filed a forfeiture complaint alleging that these Alaris products were adulterated under the FD&C Act because the pumps' quality was substandard. (SAC ¶ 69.) The complaint detailed the multiple violations of good manufacturing practice and the quality systems regulations that the FDA had identified in an inspection of the Alaris manufacturing facility. (SAC ¶ 69.) Cardinal Health suspended production, sales, and repairs of a particular Alaris model after approximately 1,300 units were seized by the FDA. (SAC ¶ 70.) In order to resolve the forfeiture action against it, Cardinal Health entered into a consent decree with the FDA on February 7, 2007 setting forth certain requirements that Cardinal Health must follow to resume the manufacture and sale of the Alaris SE pumps (the "Consent Decree"). (SAC ¶ 71.)

In June 2007, Alaris infusion pumps were subject to two Class II recalls and in October 2007 they were the subject of a Class I recall related to manufacturing defects and sterilization failures impacting approximately 200,000 units. (SAC ¶ 72.) In subsequent inspections of the manufacturing facility conducted by the FDA in early 2008, the FDA identified multiple violations of good manufacturing practice and the quality systems regulations, which the FDA reported in a Form 483 dated February 1, 2008. (SAC ¶ 73.) Following these continuing defects and violations, the Consent Decree was amended in February 2009 to include all models of the Alaris infusion pumps then produced (the "Amended Consent Decree"). (SAC ¶ 74.) The Amended Consent Decree required that Cardinal Health conduct a thorough review of all Alaris infusion pumps within sixty days and submit a corrective action plan to the FDA that outlined all planned modifications to any pump products. (SAC ¶ 75.) The Amended Consent Decree further required Cardinal Health to have an independent expert inspect and certify that the Company's infusion

pump operations were in conformity with the quality systems regulations and that the company's recall procedures and ongoing infusion pump recalls complied with the FD&C Act. (SAC ¶ 75.) The Amended Consent Decree remained in effect at all relevant times through the Class Period. (SAC ¶ 83.)

Soon thereafter, Cardinal Health spun off CareFusion, which continued to manufacture and market Alaris products. (SAC ¶ 77.)

C. BD Acquires Alaris

On October 5, 2014, BD entered into an agreement to acquire CareFusion, which at the time manufactured Alaris and other products. (SAC ¶ 78.) The acquisition closed on March 17, 2015 and CareFusion became a part of the Medication Management Solutions division within BD's Medical segment.[6] (SAC ¶ 79–81.) The acquisition doubled the size of the Medical segment. (SAC ¶ 79.) After the CareFusion acquisition, the Alaris products became a critical component in a suite of interoperable medical devices which BD manufactured and sold. (SAC ¶ 81.) Such interoperability made purchasing the suite of devices desirable to end-customers. (SAC ¶ 81–82.)

Alaris continued to suffer various defects after BD's acquisition of CareFusion. These defects resulted in five Class II recalls of certain Alaris infusion modules in 2016, and another five recalls in 2017—four of which were Class II recalls and one of which was a Class I recall. (SAC ¶¶ 91–96.) A Class II recall issued in November 2016 was the result of a software error which resulted in the failure of Alaris low battery and very low battery alarms, leaving only an alarm that

[6] Between 2002 and BD's 2015 acquisition of Alaris, Alaris manufacturers collectively filed six 510(k) applications in connection with changes and modifications to the device, at least one of which specifically concerned software-related changes. (SAC ¶ 88.) For each of these applications, the FDA issued a letter finding the device to be substantially equivalent to a predicate device and cleared Alaris for commercial distribution. (SAC ¶ 88.)

triggered once the pump's battery was depleted. (SAC ¶ 94.) This recall affected over 500,000 Alaris units. (SAC ¶ 94.)

In August 2016, BD's Regulatory Department conducted a regulatory assessment concerning whether BD was required to obtain renewed 510(k) clearance in light of various updates the Company previously made to the Alaris software and a planned update concerning the low battery alarm issues. (SAC ¶ 137.) This assessment, which took into consideration the draft guidance the FDA had released that month concerning how manufacturers should determine when a 510(k) submission was required, concluded that BD was required to file a 510(k) application encompassing these issues. (SAC ¶ 137.) The assessment was reported to "senior management," though the SAC does not allege that any of the Individual Defendants received or participated in meetings concerning the assessment. (SAC ¶ 138.) This assessment did not prompt BD to submit a 510(k) application for either the historical Alaris changes in a "catchup" submission or the low battery alarm fixes planned at that time. (SAC ¶ 138.)[7]

In November 2017, BD submitted to the FDA a 510(k) application for changes to Alaris made as part of a project named "Project Monterey." (SAC ¶¶ 139–140.) According to a former employee[8] within the Regulatory Department, Project Monterey was originally intended to include

[7] When BD made modifications to Alaris, BD's Regulatory Department would determine whether the change was "in-scope or out-of-scope," with the latter requiring BD to obtain 510(k) approval (SAC ¶ 138), though the SAC does not explain the difference between these two states. Plaintiff also alleges that individuals at BD took the position that some of the Alaris software modifications did not require 510(k) filings because the modifications were not made to the physical existing infrastructure of the pump. (SAC ¶ 129.) The SAC is otherwise bereft of detail concerning the compliance and regulatory review systems, generally, at BD.

[8] Plaintiff relies on five former employees as confidential witnesses: (i) a "senior engineer at BD from 2015 to 2019" who "worked directly on software changes to Alaris;" (ii) an individual who worked at CareFusion and then BD until "early 2019" and had "responsibilities for managing BD's quality systems;" (iii) an "Associate Director in engineering at BD from mid-2016 through late 2019" who worked directly on Alaris; (iv) a Quality Assurance Manager who worked at BD from mid-to-late 2019 with "a primary responsibility of conducting reviews of quality systems at several Alaris production facilities;" (v) an individual who worked in BD's Regulatory Department from "at least mid-2016 through the latter

in the 510(k) application "catch-up" changes to Alaris, covering changes that had been made previously without prior 510(k) approval, but the November 2017 application did not include those historical changes. (SAC ¶ 140.)[9] During the application process, the FDA asked BD questions concerning software changes that BD had made to Alaris without prior 510(k) clearance and sought an explanation regarding why prior versions of the software did not require 510(k) clearance. (SAC ¶ 141.) According to this former employee, the FDA conditioned the approval of the Project Monterey-related application on obtaining answers and data related to updates and revisions that had already been made to the device. (SAC ¶ 141.)

BD was informed in or around April 2018 that the FDA was not going to accept the November 2017 application, and BD withdrew the application by approximately June 2018. (SAC ¶ 143.) Defendant Polen subsequently directed an analysis of why the 510(k) submission for Project Monterey had failed and later received reports concerning the application's failure. (SAC ¶ 145.)

From July to September 2018, the FDA inspected BD's San Diego facility where Alaris is developed, tested, and manufactured. (SAC ¶ 146.) Based on this inspection, the FDA issued a Form 483 to BD for deficiencies identified with respect to Alaris-related quality systems and product problems. (SAC ¶ 146–147.) Among other deficiencies, the FDA identified continuing problems with respect to the low battery alarm system, which was the subject of a 2016 recall. (SAC ¶ 147.) This Form 483 was not disclosed to the public. (SAC ¶ 97.) BD submitted to the FDA in September 2018 a response to the Form 483 stating that BD Regulatory Affairs had

---

half of 2020," including at times as a "Manager." According to the SAC, this last individual worked primarily on Alaris for "long periods" of his employment. (SAC ¶¶ 127, 131, 134, 135, 175.)

[9] While the SAC makes clear that "catch-up" changes were not included within the Project Monterey-related application, it does not identify the modifications which were included in the application.

determined that 510(k) clearance was required for a software fix that was necessary to correct the low battery alarm issue. (SAC ¶ 147.) According to a former employee, BD representatives met with the FDA concerning the Alaris low battery alarm issue in August 2018 and again in March 2019, though the SAC fails to include any detail regarding the meetings' participants or discussions. (SAC ¶ 149.)

Furthermore, the SAC alleges that, "by early- to mid-2019," BD's Regulatory Department "came to the realization" that prior Alaris software modifications had required—but never received—FDA 510(k) clearance. (SAC ¶ 130.)[10] The Regulatory Department attempted to file during "mid-2019" a "catch-up" 510(k) filing that encompassed the unfiled changes and modifications. (SAC ¶ 132.) This filing attempted to obtain approval for corrections, modifications, and software patches that BD had already made to Alaris products. (SAC ¶ 132.)

In or around October 2019, the Regulatory Department conducted another regulatory assessment regarding Alaris software changes related to the low battery alarm issue. (SAC ¶ 150.)[11] Sometime in early November 2019, the Company issued a "shipping hold" on Alaris products (the "November 2019 Shipping Hold"). (SAC ¶¶ 138, 154, 159.) The November 2019 Shipping Hold was lifted in or around December 2019. (SAC ¶ 164.) The hold was lifted without the FDA's prior authorization. (SAC ¶ 164.)

---

[10] The SAC does not explain how the Regulatory Department "came to the realization" in 2019 of the need to obtain 510(k) approval when the Department was allegedly aware of this need previously. (SAC ¶¶ 137-138 (alleging that an August 2016 assessment by the Department concluded that an application was required), 139-140 (alleging that, in November 2017, Project Monterey was originally intended to include "catch-up" changes), 147–148 (alleging that, in September 2018, BD submitted a response to the FDA's Form 483 acknowledging the need for an application).)

[11] The SAC alleges that this assessment was performed "in anticipation of BD filing a 510(k) application that would include the needed software fix for the persistent Alaris low battery alarm issue." (SAC ¶ 151.) The SAC leaves the reader guessing regarding whether this 510(k) application is the same application as that which the SAC describes as a "mid-2019" "catch-up" application.

D. The Class Period and the Allegedly Misleading Statements

The SAC avers that beginning on November 5, 2019 and throughout February 6, 2020, Defendants made twenty-five statements which were allegedly misleading due to their failure to acknowledge severe issues with respect to Alaris' performance and ongoing FDA scrutiny of the device. Defendants, Plaintiff maintains, communicated information about BD that was not consistent with this awareness.

1. November 5, 2019 - Announcement of Fiscal Year 2019 Earnings and Fiscal Year 2020 Guidance

On November 5, 2019, BD issued a press release announcing its earnings for fiscal year 2019 and issuing guidance for 2020. (SAC ¶ 108.) According to the SAC, Defendants made a number of misleading statements of material fact in the press release and during an investor call conducted that day, after the issuance of the press release. These include:

- Statements regarding planned "improvements," "upgrades," and enhancements to Alaris products and discussions with the FDA about the "timing of implementations of these upgrades." The Defendants also made statements that the timing issue would shift Alaris revenue from first half FY20 to "the balance of the fiscal year." (SAC ¶¶ 270, 273.)

- Statements concerning the "ongoing momentum and share gains in [MMS]" as a key driver for fourth quarter FY19 performance." (SAC ¶¶ 267, 269, 273.)

- Statements that purportedly exaggerate the company's financial results, including revenues and earnings per share, for fiscal year 2020.[12] (SAC ¶¶ 264, 266, 267, 268, 270, 272.)

[12] In the press release, BD represented to investors that "the [C]ompany expects full fiscal year 2020 revenues to increase 4.0 to 4.5 percent as reported, or 5.0 to 5.5 percent on a currency-neutral basis" and "[a]s adjusted, the company expects full fiscal year 2020 diluted earnings per share to be between $12.50 and $12.65, resulting in growth of approximately 9.5 to 11.0 percent on a currency-neutral basis." (SAC ¶ 220.)

Plaintiff argues that, at the time of these misrepresentations, BD executives understood BD's quality systems and controls as to Alaris were not in compliance with FDA requirements and not in compliance with the obligations imposed under the Amended Consent Decree. These product problems posed significant safety issues to patients and signaled major compliance failures that were the subject of ongoing FDA scrutiny, and their remediation would in some cases require 510(k) clearance from the FDA—and hinder BD's ability to generate the Alaris revenue that Defendants repeatedly told investors supported its FY20 Guidance. (SAC ¶ 274.)

2. November 21, 2019 - Jefferies London Healthcare Conference

The SAC identifies a number of alleged misrepresentations made by John Gallagher on November 21, 2019 while he was speaking on behalf of BD at the Jefferies London Healthcare Conference. Gallagher reiterated the November 5, 2019 guidance regarding the timing of BD's expected revenue in fiscal year 2020. (SAC ¶ 280.) When asked to describe the factors driving the FY20 Guidance, he stated:

> [P]robably one of the larger ones to call out as well is Alaris pumps. We're upgrading some software. This is in our MMS business, our infusion pumps. We're upgrading some software in the pumps, and that will delay some installations and shipment into the subsequent quarters, and we anticipate getting all of that back inside of the fiscal year.

(SAC ¶ 282.) Gallagher also asserted that BD "expect[ed Alaris'] momentum to continue when you look at the full year of fiscal '20." (SAC ¶ 284.)

3. November 27, 2019 - Form 10-K

On November 27, 2019, the Company filed its FY19 Form 10-K for the period ending September 30, 2019, which was approved, signed, and certified by Defendants Forlenza and Reidy. (SAC ¶ 286.) According to the SAC, the Form 10-K made materially false or misleading statements that "characterized as contingent or speculative risks that had already come into being or that were reasonably projected to occur." (SAC ¶ 286.) Namely, according to the SAC, the

statements in the Form 10-K were at odds with the Company's failure to comply with applicable regulations,[13] failure to comply with the Amended Consent Decree,[14] and failure to obtain necessary approvals with respect to Alaris.[15]

4. December 4, 2019 - Evercore HealthCONx Conference

On December 4, 2019, Defendant Reidy attended and spoke at the Evercore HealthCONx Conference and repeated some of the purportedly misleading statements. When asked by an analyst whether "anything changed at all in the competitive side for" BD, Reidy responded: "No. Actually, the [infusion] pump side, we've been taking 200 points of share last year, and we see that

---

[13] See SAC ¶ 287 ("Our failure to comply with the applicable good manufacturing practices, adverse event reporting, and other requirements of these agencies could delay or prevent the production, marketing or sale of our products and result in fines, delays or suspensions of regulatory clearances, warning letters or consent decrees, closure of manufacturing sites, import bans, seizures or recalls of products and damage to our reputation.").

[14] See SAC ¶¶ 288 ("While this BD organizational unit remains subject to the amended consent decree, which includes the requirements of the original consent decree, it has made substantial progress in its compliance efforts . . . [but] [w]e may be obligated to pay more costs in the future because, among other things, the FDA may determine that we are not fully compliant with the amended consent decree and therefore impose penalties under the amended consent decree . . . . As of September 30, 2019, we do not believe that a loss is probable in connection with the amended consent decree . . . ."), 289 ("The consent decree authorizes the FDA, in the event of any violations in the future, to order us to cease manufacturing and distributing products, recall products or take other actions, and we may be required to pay significant monetary damages if we fail to comply with any provision of the consent decree.").

[15] See SAC ¶¶ 290 ("Delays in obtaining necessary approvals or clearances from the FDA or other regulatory agencies or changes in the regulatory process may also delay product launches and increase development costs . . . [and] [m]anufacturing or design defects, component failures, unapproved or improper use of our products, or inadequate disclosure of risks or other information relating to the use of our products can lead to injury or other serious adverse events. These events could lead to recalls or safety alerts relating to our products . . . and could result, in certain cases, in the removal of a product from the market. . . . In some circumstances, such adverse events could also cause delays in regulatory approval of new products or the imposition of post-market approval requirements."), 291 ("BD actively maintains FDA/ISO Quality Systems that establish standards for its product design, manufacturing, and distribution processes. Prior to marketing or selling most of its products, BD must secure approval from the FDA and counterpart non-U.S. regulatory agencies. . . . These regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction, and continued availability of new products. . . . These agencies possess the authority to take various administrative and legal actions against BD, such as product recalls, product seizures and other civil and criminal sanctions.").

continuing, and we have some visibility to that. So we don't see that being the case." (SAC ¶ 295.) Reidy also referred to the "great advantages" that Alaris provided by virtue of connectivity across BD's product lines. (SAC ¶ 295.) Furthermore, Reidy also made several statements concerning revenue deferrals in the Alaris product line, referring to these deferrals as a result of "a timing issue." (SAC ¶ 297.)

5. January 14, 2020 - JPMorgan Healthcare Conference

On January 14, 2020, Defendants Reidy and Polen attended and spoke at the JPMorgan Healthcare Conference and presented an investor slide deck entitled "Introducing the Next Phase of Value Creation for BD," which was published on BD's website. Polen re-affirmed BD's FY20 Guidance and once more reassured investors that BD was "very much on track for the full year" FY20 Guidance. (SAC ¶¶ 300–01.) Defendant Polen declared that BD had "[f]ully resumed shipping [Alaris products] in the first quarter." (SAC ¶ 304.) When asked by an analyst whether the shipping deferral "played out as expected," Polen responded: "Exactly as expected." (SAC ¶ 305.)

6. January 28, 2020 - Annual Shareholders Meeting

On January 28, 2020, the Company held its Annual Shareholders Meeting and provided investors with a presentation entitled "Annual Meeting of Shareholders," which was published on BD's website. During the shareholders' meeting, Defendant Forlenza again represented that BD was "on track" to meet its FY20 Guidance. (SAC ¶¶ 308–09.)

7. February 4, 2020 - BD's Voluntary Recall Notification

On February 3, 2020, BD representatives met with FDA representatives for an "in-depth discussion" concerning Alaris and the need for 510(k) approval. (SAC ¶ 305.) The next day, on February 4, 2020, BD issued a voluntary recall notification and recall letters to address certain software issues with Alaris (the "February 4 Recall Notices" or the "Recall Notices"). (SAC

¶ 312.) In the February 4 Recall Notices, BD advised customers that it would undertake "comprehensive education and support" concerning the software issues and patch "an upcoming software release." (SAC ¶ 312.) The February 4 Recall Notices did not disclose that the FDA had informed BD that it needed 510(k) clearance for the previously implemented software changes. (SAC ¶¶ 206–13.)

E. BD Discloses the Need for 510(k) Approval

On February 6, 2020, BD issued a Form 8-K with an attached earnings press release disclosing that the FDA required BD to obtain 510(k) clearance for historical software changes and that BD was required to halt all Alaris sales. (SAC ¶ 218.) It also lowered its Company-wide earnings guidance for FY20 and lowered the forecast for Alaris revenues to zero for the balance of FY20. (SAC ¶ 220.) Shortly after the issuance of the earnings release, BD held a pre-market conference call regarding BD's first quarter FY20 earnings during which Polen discussed the new guidance and the Company's February 3, 2020 meeting with the FDA:

> Through our ongoing dialogue with the FDA, including in-depth discussion this past Monday, we learned that the FDA disagreed with our conclusion about the need for a new 510(k) clearance for these software upgrades. And in light of the consent decree, the FDA has requested that we combine all Alaris software enhancements, recall remediation updates and changes made to the Alaris system over time into a single comprehensive 510(k) filing, which we're going to submit in the fourth quarter of FY '20. We're actively continuing to collaborate with the FDA to ensure we meet their expectations for this upcoming regulatory submission.

(SAC ¶ 224.) According to the SAC, upon the disclosure of the news BD's stock price declined $33.74—nearly 12%—on February 6, 2020 with unusually heavy trading volume. (SAC ¶ 235.)

A month later, on March 6, 2020, the FDA categorized BD's February 4, 2020 recall as a Class I recall affecting over 750,000 devices. (SAC ¶ 241.)

F. Individual Defendants Forlenza's and Polen's Trading Histories

During the Class Period, Defendant Forlenza sold 198,137 shares of BD common stock for total proceeds of $54,668,240.95. Nearly all Forlenza's sales were made pursuant to a 10b5-1 trading plan that he entered on December 16, 2019—during the Class Period. Defendant Polen sold 13,907 shares of BD common stock during the Class Period—all of which were sold on or about December 16, 2019—for total proceeds of $3,749,744.41.[16]

II. DISCUSSION

On a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must apply the standard of review articulated by the Supreme Court in Bell Atlantic Corp. v. Twombly and Ashcroft v. Iqbal. Under this standard, a complaint will survive a motion under Rule 12(b)(6) only if it states "sufficient factual allegations, accepted as true, to 'state a claim for relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic v. Twombly, 550 U.S. 544, 570 (2007)). A complaint states a plausible claim if it "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (citing Twombly, 550 U.S. at 556). While the complaint need not demonstrate that a defendant is probably liable for the wrongdoing, allegations that give rise to the mere possibility of unlawful conduct will not do. Iqbal, 556 U.S. at 678; Twombly, 550 U.S. at 557.

A. Securities Fraud Claim Under § 10(b) of the Exchange Act

Section 10(b) of the Exchange Act provides that a person or entity may not "use or employ, in connection with the purchase or sale of any security, . . . any manipulative or deceptive device

[16] The SAC does not allege that Defendant Reidy conducted any insider sales during the Class Period.

or contrivance in contravention of [SEC] rules and regulations." 15 U.S.C. § 78j(b). Rule 10b-5(b), in turn, makes it unlawful to "make any untrue statement of material fact or to omit to state a material fact in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b)(2). The Supreme Court has recognized a private cause of action for damages sustained as the result of a violation of Section 10(b) and Rule 10b-5. Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 341–42 (2005). To state a claim under Rule 10b-5, a plaintiff must allege facts establishing each of the following elements: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. Id.; City of Edinburgh Council v. Pfizer, Inc, 754 F.3d 159, 167 (3d Cir. 2014). A failure to plead any one of these elements in accordance with the pleading standard applicable to a securities fraud claim prevents a plaintiff from stating a legally sufficient claim. Dura, 544 U.S. at 346-47.

In evaluating a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court "must consider the complaint in its entirety, as well as . . . documents incorporated into the complaint by reference, and matters of which the court may take judicial notice." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007). In that regard, the Third Circuit has held that a district court may take judicial notice of documents "integral to or explicitly relied upon in the complaint," SEC filings, and stock price data. In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1331 (3d Cir. 2002) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997)).

Defendants challenge the sufficiency of the Rule 10b-5 claim on several grounds. They argue that the SAC fails to set forth particularized facts indicating why the alleged actionable statements and omissions were misleading, fails to plead scienter with the requisite particularity, and fails to plead loss causation.

1. Plaintiff fails to allege material misstatements or omissions.

To allege a material misstatement or omission under Rule 10b-5, Plaintiff must plead with particularity that Defendants "made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading." Oran v. Stafford, 226 F.3d 275, 282 (3d Cir. 2000) (quotations omitted). Claims brought pursuant to Section 10(b) of Exchange Act and the statute's implementing regulation Rule 10b-5 are subject to certain heightened pleading requirements under the PSLRA. Tellabs, 551 U.S. at 320–21 (noting that prior to the enactment of the PSLRA, the pleading standard of Rule 9(b) governed the sufficiency of a complaint for securities fraud). The PSLRA mandates that, to survive a motion to dismiss, a complaint must (1) "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed" and (2) "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. §§ 78u-4(b)(1) & (2); 15 U.S.C. § 78u-4(b)(3)(2) ("In any private action arising under this chapter, the court shall, on the motion of any defendant, dismiss the complaint if the requirements of [15 U.S.C. §§ 78u-4(b)(1) & (2)] are not met."). The PLSRA's particularity requirement echoes the heightened standard set forth in Federal Rule of Civil Procedure 9(b), applicable to general claims of fraud. Institutional Investors Group v. Avaya, Inc., 564 F.3d 242, 253 (3d Cir. 2009).

It is well-established that "[a]bsent a duty to disclose, silence is not fraudulent or 'misleading under Rule 10b-5.'" United States v. Schiff, 602 F.3d 152, 162 (3d Cir. 2010) (quoting Basic Inc. v. Levinson, 485 U.S. 224, 239 n.17 (1988)); see also Burlington Coat Factory, 114 F.3d at 1432 ("Except for specific periodic reporting requirements[,] . . . there is no general duty on the part of a company to provide the public with all material information."). A duty to disclose

under Rule 10b-5 may arise in three circumstances: "when there is insider trading, a statute requiring disclosure, or an inaccurate, incomplete or misleading prior disclosure." Oran, 226 F.3d at 285-286. An omission may constitute a violation of Rule 10b-5 only where there is "'a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." MatriXX Initiatives, Inc. v. Siracusano, 563 U.S. 27, 38 (2011) (quoting Basic, 485 U.S. at 231-232); see also Oran, 226 F.3d at 282 (holding same).

At the heart of Plaintiff's allegations is the contention that the Defendants failed to disclose either (i) that the FDA required or would require a 510(k) application be filed and approved before BD could continue to market and sell Alaris products or (ii) the Company had previously determined that 510(k) approval would be required for the continued marketing and sale of Alaris products. Underlying these conclusions are Plaintiff's claims that Defendants failed to disclose that Alaris suffered from "pervasive" defects, which BD had attempted to correct through numerous modifications without FDA clearance over a five-year period, placing the product at imminent risk of adverse FDA action and the Company at risk of missing guidance.

The regulatory regime under which the Company operates gives to the Company, in the first instance, the discretion in whether to submit a 510(k) application.[17] Defendants were under no obligation to predict—and disclose that prediction—whether the FDA would conclude that a new 510(k) clearance was required in order to continue marketing the Alaris suite. As the Second Circuit has put it, "disclosure is not a rite of confession, and companies do not have a duty to

[17] Plaintiff argues that, since the FDA informed the Company at a February 3, 2020 meeting that it would require a 510(k) application, and did so in the absence of an active 510(k) application, the Company's determination "is not afforded the deference Defendants' suggest." (Opp. at 26 n.13.) This is an unremarkable tautology—if a company decides not to submit a 510(k) application, of course any disagreement that the FDA may have will arise in the absence a 510(k) application.

disclose uncharged, unadjudicated wrongdoing." City of Pontiac Policemen's and Firemen's Retirement System v. UBS AG, 752 F.3d 173, 183–84 (2d Cir. 2014); see also Jaroslawicz v. M&T Bank Corp., 962 F.3d 701, 717 (3d Cir. 2020), cert. denied, 141 S. Ct. 1284, 209 L. Ed. 2d 19 (2021) ("[I]t was not the future threat of regulatory action that triggered the need for disclosure under Item 105. Rather, it was the failure to disclose the risks associated with the compliance program."); McClain v. Iradimed Corp., 111 F. Supp. 3d 1293, 1305 (S.D. Fla. 2015) (no obligation to disclose potential FDA action against company when it received a critical Form 483).

Plaintiff contends that, notwithstanding whether the FDA informed Defendants that a new application would be required prior to the continued marketing of the Alaris products, Defendants subjectively believed that an application would need to be filed, and thus the failure to disclose this belief was a misleading omission. The SAC is replete with allegations that, beginning in 2016, various individuals and departments at the Company concluded that BD was required to file a 510(k) application for prior and proposed software changes to the Alaris products. Indeed, the SAC goes so far as to allege that BD (i) in November 2017 submitted a 510(k) application in connection with Project Monterey that was "originally intended to include 'catch-up' changes that BD had previously determined needed 510(k) approval" for Alaris products, in connection with which the FDA indicated that it would require information regarding prior software changes before granting 510(k) approval for Project Monterey-related changes; (ii) in September 2018 received from the FDA a Form 483 identifying continued deficiencies with respect to Alaris's low battery alarm systems; and (iii) in "mid-2019" "attempted to file" a 510(k) application in connection with "corrections, modifications, and software patches that BD had already made to Alaris products." (SAC ¶ 132). Accepting these allegations as true, they are still insufficient to establish that the Individual Defendants believed that a 510(k) application would be necessary. See infra at 33.

Here, the SAC alleges that the FDA was well-aware of the various pending software updates and potential problems with the Alaris products prior to the Class Period, yet the agency did not act against the Company until February 3, 2020. Absent a demonstration that the FDA had in some manner or other made clear that it would require a new 510(k) application for Alaris products, and that BD would be required to stop marketing Alaris until that application was successfully resolved, the mere possibility of administrative action is not enough to require disclosure.

The allegations are insufficient to establish that Defendants knew or even believed that the FDA was going to require a 510(k) application for Alaris prior to the continued marketing of the devices, nor were they obligated to predict the regulatory action that the FDA would ultimately take.[18] Accordingly, the failure to disclose the 510(k) application is actionable only if disclosure was necessary to render the relevant statements not misleading.

i. *Allegedly misleading statements regarding the nature of the Alaris software changes are not actionable.*

Plaintiff contends that the Company's characterizations of the Alaris software modifications were misleading, as these "updates," "enhancements," and "improvements" were in actuality "critical remediation addressing acute threats to patient safety." (SAC ¶¶ 270, 272–273, 282; Opp. at 17.) Phrasing the changes as such also, according to Plaintiff, "impl[ied] that 510(k) clearance . . . was unnecessary and that the FDA had countenanced their implementation without further review." (Opp. at 17.) Plaintiff argues that Defendants' statements further served to

[18] Similarly, Defendants were under no standalone obligation to disclose the Form 483 that BD received from the FDA in 2018. Forms 483 provide "interim FDA feedback," Schaeffer v. Nabriva Therapeutics plc, 2020 WL 7701463, at *9 (S.D.N.Y. Apr. 28, 2020), and failure to disclose it is actionable only if its disclosure is necessary to remediate otherwise misleading statements.

obscure the fact that the November 2019 Shipping Hold was part of a "continuing 'software remediation plan'" which should have been disclosed. (Opp. at 19.)

Defendants' characterizations of the software modifications do not amount to actionable statements. There can be no doubt that these statements are not alleged to be false: The modifications in question were "upgrades," "enhancements" and "improvements," whether or not they were implemented to "remediate" or "fix" previously identified issues. There is no half-truth about it, and Plaintiff's disagreement with those terms amounts to mere pedantry. Furthermore, Defendants' statements must be evaluated in the context of all available information. Omnicare, Inc. v. Laborers Dist. Council Const. Ind. Pension Fund, 575 U.S. 175, 190 (2015)). This mix of information includes the Company's disclosure of its ongoing dialogue with the FDA must be considered with the totality of the available information, which includes, as the SAC makes abundantly clear, problems with the Alaris suite of products. (Opp. at 6 ("In 2016 and 2017 alone, various Alaris models were the subject of no fewer than ***ten*** FDA Class I and II recalls, several concerning software defects that could impede functioning, jeopardizing patient health.") (emphasis in original).) Considering the available information, no reasonable investor could bury their head in the sand to avoid the potential risks of regulatory action against the Alaris products. Cf. In re Amarin Corp. PLC Sec. Litig., 689 F. App'x 124, 132 (3d Cir. 2017) (quoting Tongue v. Sanofi, 816 F.3d 199, 211 (2d Cir. 2016)) ("[A] reasonable investor understands that a '[c]ontinuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process.'") (alteration in original).

For similar reasons, the use of the terms at issue did not give rise to the "impl[ication] that 510(k) clearance . . . was unnecessary," nor that "the FDA had countenanced [the software modifications'] implementation without further review." (Opp. at 17.) Defendants are not alleged

to have made any statements regarding 510(k) approval for Alaris until the allegedly corrective disclosures. And, as early as November 5, 2019, the Company disclosed that it was "in discussions with the FDA" regarding software upgrades concerning "alarm prioritization and optimization" and a "new software release." (Smith Decl. Ex. C at 8.) Also well-known was the fact that a 510(k) application for Alaris had not been completed since 2015, notwithstanding the continuing pattern of Alaris' deficiencies, including at least one recall that concerned Alaris's alarms. (SAC ¶ 89.) Particularly when viewed in conjunction with the Company's disclosures concerning the risks that an adverse FDA determination could pose to BD's business, not least of which includes heightened scrutiny of the Alaris devices pursuant to the Amended Consent Decree, no reasonable investor could conclude that the FDA had "countenanced [the software updates'] implementation without further review" (Opp. at 17). See In re Amarin, 689 F. App'x at 132. Likewise, the fact that Defendant Reidy claimed on the November 5 earnings call that the Company was "in discussion with the FDA about the timing of implementation" of the upgrades and new software release (SAC ¶ 270) was neither misleading nor a false characterization of the FDA's position on the Alaris products. Compare with In re Mannkind Sec. Actions, 835 F. Supp. 2d 797 (C.D. Cal. 2011) (refusing to dismiss claims where defendants claimed that the FDA had "blessed," "approved," "accepted," and "agreed to" the company's methodological approach in its clinical trials, when it later became evident that the FDA had not done so).

Plaintiff also asserts that Defendants' statements obscured the fact that the November 2019 Shipping Hold was part of a "continuing 'software remediation plan,'" and thus were inaccurate or misleading. (Opp. at 19.) According to Plaintiff, the Shipping Hold was enacted to address safety and compliance problems identified in the fourteen months prior to the Shipping Hold. Plaintiff largely relies on the reporting of two confidential witnesses in supporting this contention.

An individual employed in the Regulatory Department during the Class Period ("FE-5") was "certain" that "some of the very same issues that led to the November 2019 Alaris shipping hold also underlay the broad Alaris recall that BD announced . . . in February 2020." (SAC ¶ 154.) Furthermore, a former employee within BD's Engineering Department ("FE-3") "understood" that when an FDA auditor learned of the "trackers" "during the course of an audit in 2019" "Alaris product shipments were put on hold by no later than October 31, 2019." (SAC ¶ 157.)

When considering allegations made by confidential witnesses, courts should assess the "'detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia.'" Avaya, 564 F.3d at 261 (quoting Chubb, 394 F.3d at 147). If, after that assessment, "anonymous source allegations are found wanting with respect to these criteria ... [courts] must discount them steeply." Id. at 263.[19] In instances where, as here, the complaint includes speculation under the guise of factual assertions, such a discount is warranted. The SAC fails utterly to ascribe the basis for FE-5's "certainty" that the November 2019 Shipping Hold was tied to the February 2020 recall announcement.[20] Meanwhile, FE-3's "understanding" allegedly stems from a conversation he had with a superior on October 31, 2019 during which his superior told him "that BD was going to put a shipping hold on Alaris." (SAC ¶ 158.) While this conversation speaks to when FE-3 learned

[19] While a confidential witness need not have a "direct link" to Defendants, such an absence certainly weighs on the plausibility of allegations sourced to the witness. Avaya, 564 F.3d at 268–69.

[20] See also SAC ¶ 161 ("FE-5 came to understand in the course of his continuing work on Alaris regulatory issues that the FDA became aware of the numerous software anomalies related to Alaris during 2019.") (emphasis added).

of the impending hold on Alaris products, it conspicuously excludes any basis for FE-3's conclusion that the November Shipping Hold had anything to do with the FDA's audit.

Beyond these allegations, Plaintiff relies on inference and conjecture to tie the November 2019 Shipping Hold to purported problems with Alaris when it argues:

> In the fourteen months prior, the FDA had criticized BD's failure to seek 510(k) clearance for earlier changes issued BD a Form 483 following an inspection citing various compliance problems and Alaris defects (including the LBA issue), directed BD to recall Alaris to fix the KVO problem, discovered a litany of "trackers" on software anomalies that BD had long failed to fix, rejected BD's "catch-up" 510(k) application, and demanded that BD undertake a full review of all Alaris changes made over the past five years.

(Opp. at 18 n.7 (internal citations omitted).) The combination of vague allegations by confidential witnesses and the speculative inferences that Plaintiff offers up are insufficient to conclude that Defendants' descriptions of the updates were misleading, let alone false.

Similarly, statements made in January 2020 regarding the Q1 2020 sales—that BD had "fully resumed shipping in the first quarter" and was "back to shipping in Q1 to the majority of [BD's] customers" (SAC ¶ 304), and that this was "exactly as expected" (SAC ¶ 305)—are not alleged to be false.[21] And, while Plaintiff argues that the latter statement was misleading because BD did not have the FDA's approval to market the Alaris devices, for the reasons discussed, Defendants were not obligated to predict that the FDA would take regulatory action against the Company. See supra at 21.

[21] Furthermore, Defendant Polen's statement that the circumstances played out as "expected" is an opinion by which liability may not lie unless Plaintiff has pleaded sufficiently that Polen did not in fact believe it. Omnicare, 575 U.S. 175, 186 (2015) (quotations omitted). Plaintiff has not done so here. See infra at 33.

ii. *Allegedly misleading risk disclosures within the 10-K are not actionable.*

According to Plaintiff, disclosures found in BD's 10-K were misleading insofar as certain of these risks had already materialized. "Cautionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired." S.E.C. v. Tecumseh Holdings, 765 F.Supp.2d 340, 352 (S.D.N.Y.2011) (emphasis in original) (quoting Rombach v. Chang, 355 F.3d 164, 173 (2d Cir.2004)); see e.g., In re MobileMedia Sec. Litig., 28 F. Supp. 2d 901, 930 (D.N.J. 1998) (finding allegation that defendants' warning of possible difficulties with acquired company's subscriber base actionable when they were already experiencing integration difficulties).

Plaintiff contends that the warnings in the Company's 10-K concerning BD's potential "failure to comply with the applicable good manufacturing processes, adverse event reporting, and other requirements of these agencies [including the FDA] could delay or prevent the production or sale of our products" (SAC ¶¶ 287, 289, 290, 291), was misleading insofar as these risks had already materialized. But this risk focuses on the possibility that an agency determination could impact the sale of Alaris products. Williams v. Globus Med., Inc., 869 F.3d 235, 242 (3d Cir. 2017) ("The risk actually warned of is the risk of adverse effects on sales – not simply the loss of independent distributors generally. Accordingly, the risk at issue only materialized – triggering Globus's duty to disclose – if sales were adversely affected at the time the risk disclosures were made.").[22] This risk is not manifest until the Company is aware of such a determination which, as discussed supra p. 24, Plaintiff has not sufficiently pleaded existed at the time of the 10-K.

[22] The authorities Plaintiff cites in opposition are inapposite insofar as they concern risks that had already materialized at the time of the misleading statements See In re Westinghouse Sec. Litig., 90 F.3d 696, 709-10 (3d Cir. 1996) (warning of future impact to loan losses where company knew current reserves were insufficient at the time of the statement); In re MobileMedia, 28 F. Supp. 2d at 930 (warning of possible "unforeseen" difficulties in the integration of an acquisition when the company was already experiencing such difficulties); see also Meyer v. Jinkosolar Holdings Co., Ltd., 761 F.3d 245, 251 (2d Cir. 2014)

Finally, Plaintiff complains that the 10-K misleadingly touts BD's "substantial progress in its compliance efforts." (SAC ¶ 288.) Even if Plaintiff had pleaded facts sufficient to demonstrate the falsity of this statement—it is not evident from the SAC that the Company had not in fact improved its compliance efforts with the Amended Consent Decree—no reasonable investor could rely on such a "simple and generic assertion[]" about BD's compliance efforts. Singh v. Cigna Corp., 918 F.3d 57, 64 (2d Cir. 2019).

iii. *Allegedly misleading statements regarding the Company's FY20 revenues and earnings guidance are not actionable.*

The PSLRA contains a "safe harbor" provision that immunizes defendants from liability under Section 10(b) for "forward-looking statements," such as statements of future economic performance. 15 U.S.C. §78u–5(i)(1)(B). This immunity applies if the forward-looking statement is identified as such and "is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement" or the plaintiff fails to prove the forward-looking statement "was made with actual knowledge by [the speaker] that the statement was false or misleading . . . ." OFI Asset Mgmt. v. Cooper Tire & Rubber, 834 F.3d 481, 490 (3d Cir. 2016) (quoting 15 U.S.C. §78u–5(i)(1)(B)).

(statements about compliance measures found misleading where company's measures were already failing to perform sufficiently); Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 986-87 (9th Cir. 2008) ("Nothing alerts the reader that some of these risks may already have come to fruition, and that what the company refers to as backlog includes work that is substantially delayed and at serious risk of being cancelled altogether."); In re BHP Billiton Ltd. Sec. Litig., 276 F. Supp. 3d 65, 81 (S.D.N.Y. 2017) (finding statements concerning management's "relentless" commitment to safety misleading where defendants already were aware of extensive and serious problems with a dam that later failed); In re Facebook, Inc. IPO Sec. & Deriv. Litig., 986 F. Supp. 2d 487, 516 (S.D.N.Y. 2013) (warning of a potential revenue decrease where company had already experienced such an impact on revenue and revenue growth).

Plaintiff laments that Defendants subdivide the statements at issue into "distinct utterances," yet elsewhere notes (correctly) that certain elements of the purportedly forward-looking statements are in fact statements of the then-present. These excerpts concerning the then-present state of the Company's business—including those that characterize the status of the Alaris upgrades or refer to the Company's "momentum" at the time the statements were made[23]—are not entitled to protection under the PSLRA's safe harbor provisions. Avaya, 564 F.3d at 255 ("[A] mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present."); In re Dr. Reddy's Lab'y Ltd. Sec. Litig., 2019 WL 1299673, at *18 (D.N.J. Mar. 20, 2019) ("The mere fact that a statement contains some reference to a projection of future events cannot sensibly bring the statement within the safe harbor if the allegation of falsehood relates to non-forward-looking aspects of the statement."). Still, Plaintiff fails to establish that these statements were false or misleading at the time they were made. For example, Plaintiff does not allege that the Company's Alaris sales were slowing at the time Defendant Polen represented that the 2021 guidance reflected "continued momentum" in its businesses. Plaintiff's proposed conclusion relies on an FDA determination that Alaris products could no longer be marketed, a risk that was not manifest as of the time the statements were made.

Cautionary statements "do not have to be in the same document as the forward-looking statements." In re Merck & Co. Sec. Litig., 432 F.3d 261, 273 n.11 (3d Cir. 2005). With respect

[23] SAC ¶¶ 267 ("[Y]ou will see our initial guidance . . . reflects continued momentum across our businesses . . ."), 269 ("As expected, fourth quarter performance in the Medical segment was driven by ongoing momentum and share gains in Medication Management Solutions . . . ."), 273 ("I would just say in terms of momentum, maybe just one other comment there on your question, we saw in FY '19 near or at, I'd say, record levels of continued share gain both in the infusion and the dispensing business . . . ."), 295 ("Actually, the pump side, we've been taking 200 points of share last year, and we see that continuing, and we have some visibility to that. So we don't see that being the case."), 297 ("That's a timing issue. First half issue, yes."), 300 (I'd say our first quarter is consistent with the guidance we've provided in November, and we remain very much on track for the full year.").

to oral forward-looking statements, the requirement of having "meaningful cautionary statements" can be met either when the statement itself is directly accompanied by such a disclaimer, or when the speaker directs listeners to another specific document that includes meaningful cautionary statements. 15 U.S.C. § 78u–5(c)(2). "Although cautionary language need not directly accompany a challenged statement, there must be some attempt to incorporate the cautionary language 'by reference' as part of the challenged statement. Carmignac Gestion, S.A. v. Perrigo Co. PLC, 2019 WL 3451523, at *12 (D.N.J. July 31, 2019).

Certain of Defendants' forward-looking statements are couched satisfactorily with appropriate disclaimers.[24] The statements made within BD's November 5, 2019 press release and during the subsequent conference call are accompanied by meaningful cautionary language.[25] Similarly, Defendants' can rely on the disclosures within the November 27, 2019 10-K—which disclaims the potential risks to BD's business that could arise from "[d]elays in obtaining necessary approvals or clearances from" the FDA and further describes the potential risks of regulatory action against the Company in light of the continuing application of the Amended Consent Decree (Smith Decl. Ex. A at 40-42)—to inoculate themselves for statements made during the January 14, 2020[26]

---

[24] See SAC ¶¶ 264, 266, 267–68, 280, 284, 301, 308–09.

[25] See Smith Decl. Ex. J at Ex. 99.1 ("This press release, including the section entitled 'Fiscal 2020 Outlook for Full Year', contains certain estimates and other forward-looking statements (as defined under Federal securities laws) regarding BD's performance, including future revenues and earnings per share. All such statements are based upon current expectations of BD and involve a number of business risks and uncertainties. Actual results could vary materially from anticipated results described, implied or projected in any forward-looking statement. With respect to forward-looking statements contained herein, a number of factors could cause actual results to vary materially. These factors include, but are not limited to risks relating to … difficulties inherent in product development …; product efficacy or safety concerns resulting in product recalls or actions being taken by the FDA or other regulators …."); Smith Decl. Ex. C at 4 (referring listeners to the press release issued earlier in the day).

[26] See Smith Decl. Ex. K at 4 ("I will make some forward-looking statements. Factors that could cause our actual results to differ appear in our fourth quarter press release and our recent SEC filings.").

conference and the January 28, 2020[27] shareholder meeting. However, statements Defendants made at the November 21, 2019 and December 4, 2019 conferences fail to direct listeners to any cautionary language, let alone the November 10-K and its disclosures. Still, as described elsewhere (see infra at 33–41), Plaintiff has failed to demonstrate that Defendants made these statements with "actual knowledge" that they were false or misleading. Accordingly, the statements are not actionable. OFI Asset Mgmt., 834 F.3d at 490.

Plaintiff puts forth an alternative, albeit unavailing, angle for success on this claim as it relates to statements regarding the Company's internal forecasts. While "[t]he federal securities laws do not obligate companies to disclose their internal forecasts . . . if a company voluntarily chooses to disclose a forecast or projection, that disclosure is susceptible to attack on the ground that it was issued without a reasonable basis." In re Burlington Coat Factory, 114 F.3d at 1427. A projection lacks a reasonable basis if it was made after inadequate consideration of available information. Id. at 1429. Plaintiff here argues that BD's Alaris-related revenues were in "acute jeopardy . . . due to defects and other problems threatening patient safety and BD's various compliance failures." (Opp. at 27) (internal citations omitted).[28] The inferences that Plaintiff proposes that the Court adopt, however, are plead insufficiently to conclude that the projections at issue failed to have a "reasonable basis." Namely, BD's revenues were at risk if the FDA took adverse action against the Company. Particularly considering the FDA's history of inaction in the

---

[27] See Smith Decl. Ex. M at 6 ("We have information posted on our website regarding forward-looking statements and non-GAAP financial measures, which we will be using in today's presentation.").

[28] Plaintiff also argues that "BD had a concrete indication that the FDA would take further action" as a result of the November 2019 Shipping Hold. (Opp. at 27.) The SAC is insufficient to sustain the conclusion that the November 2019 Shipping Hold was a result of FDA action. See supra at 24.

face of purported compliance violations by the Alaris suite of products, the Court cannot conclude that Defendants failed to have a reasonable basis in making these projections.[29]

iv. *Allegedly misleading statements within the February 4 Recall Notices are not actionable.*

According to Plaintiff, the February 4 Recall Notices "misleadingly downplay[ed]" the problems with the Alaris devices by promising to remediate those problems with education, training, and a future software upgrade, and by failing to include the fact that BD would require new 510(k) clearance for the devices. (Opp. at 13-14.) Like its other challenges, Plaintiff does not contend that these purported flaws in the Recall Notices consist of outright falsities, and instead pursues a theory in which the Recall Notices were misleading in their omission of certain information. This argument fails for reasons already discussed. See supra at 22–24.[30]

Furthermore, Plaintiff contends that the Recall Notices were misleading insofar as they omitted that the devices were "unsuitable for continued use or that any device would be removed from the market or unavailable for sale or installation." (Opp. at 13-14.) This challenge fails for the simple fact that Plaintiff has failed to allege its underlying premise: Nowhere in the pleadings does Plaintiff allege that the devices that had been delivered and installed were or became

[29] Furthermore, the cases Plaintiff cites in support of its argument are distinguishable insofar as they each conclude that the defendants in those actions had the requisite scienter. Compare infra at 33 with In re AT&T Corp. Sec. Litig., 2002 WL 31190863, at *15 (D.N.J. Jan. 30, 2002) (sustaining claim that "defendants' statements were patently unreasonable because at the time defendants were promising revenue growth in the Business Services unit, [they] w[ere] being appraised of the serious operational problems within that unit"); City of Hialeah Emps.' Ret. Sys. & Laborers Pension Tr. Funds for N. Cal. v. Toll Bros., Inc., 2008 WL 4058690, at *2 (E.D. Pa. Aug. 29, 2008) (sustaining Section 10(b) claim that company's "projections lacked any reasonable basis" due to then-existing facts regarding softening in demand and business delays).

[30] It is not clear whether Plaintiff contends that Defendants' styling of the notice as "voluntary" was misleading. In any event, the FDA oversees both "voluntary" and "mandatory" recalls under separate authorities. Compare 21 C.F.R. § 7 (discussing voluntary recalls) with 21 C.F.R. § 810 (discussing mandatory recalls). Plaintiff has not alleged that the February 4 Recall Notices were issued pursuant to a mandatory recall order and Defendants' characterization of the recall tracks language endorsed by the FDA.

unusable, notwithstanding the existence of the recall. Instead, the SAC alleges that the February 4 Recall Notices provided "important user actions to help mitigate the potential risks until [the relevant] software issues have been remediated." (SAC ¶ 214 (quoting the February 4 Recall Notices).)[31]

2. Plaintiff fails to plead scienter

Both the PSLRA and Federal Rule of Civil Procedure 9(b) impose heightened pleading requirements on plaintiffs who allege securities fraud. Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." The PSLRA more specifically requires that a securities fraud complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2). A plaintiff may establish this strong inference "either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." In re Burlington Coat Factory, 114 F.3d at 1418. A "strong" inference is "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324. In analyzing scienter, moreover, the Court considers "not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged." Id, 551 U.S. at 314.

To evaluate the scienter of a corporate defendant such as BD, courts "look to the state of mind of the individual corporate official or officials who make or issue the statement . . . ." C. of Roseville Emps.' Ret. Sys. v. Horizon Lines, Inc., 713 F. Supp. 2d 378, 402 (D. Del. 2010). A

[31] While the Court need not explore it here, the FDA's regulations regarding the contents of recall communications, such as the requirement to omit "statement[s] that may detract from the [recall's] message, present the potential for conflict with the Company's disclosure obligations under the securities laws. See 21 C.F.R. § 7.49.

corporate defendant cannot be held liable "absent a showing that at least one individual officer who made, or participated in the making of, a false or misleading statement did so with scienter." Id. at 403 (citation omitted).

i. *Plaintiff has not established facts sufficient to support the inference of personal knowledge.*

The SAC is replete with allegations demonstrating the various problems with the Alaris software. What is absent, however, are allegations sufficient to demonstrate that the Individual Defendants acted with personal knowledge. In its efforts to establish that these individuals acted with scienter Plaintiff primarily relies on allegations made by certain unidentified former employees and by implication from the Defendants' post-Class Period statements.

The SAC includes only two allegations that go directly to the Individual Defendants' scienter. The first is the conclusory allegation that "Defendants . . . knew or had access to information reflecting . . . [that the Alaris] infusion quality process and system . . . did not meet FDA's expectations." (SAC ¶ 173.) Additionally, according to a former employee within BD's Regulatory Department who worked on Alaris products, Defendant Polen "directed an analysis of why the 510(k) submission . . . had failed" following the withdrawal of the 2017 Project Monterey application, and Polen subsequently "received reports concerning the failure of the Project Monterey 510(k) application and the reasons therefor." (SAC ¶ 145.) This, according to Plaintiff, "supports the inference that BD's top brass knew that Alaris revenues were imperiled as the Class Period began." (Opp. at 42.) Even assuming, arguendo, that Plaintiff has sufficiently pleaded the basis of this confidential witness's knowledge by virtue of the employee's area of responsibility, Plaintiff stretches the allegation too far. The SAC makes clear that the Project Monterey application did not seek approval for prior software versions, and absent from the SAC are allegations concerning the content of any reporting to Defendant Polen. Particularly given the

FDA's inaction following this application, the far more compelling inference drawn from the SAC is that Polen did not believe that the FDA would require a comprehensive 510(k) filing.

Other than these two, Plaintiff's allegations—supported by confidential witnesses who are not alleged to have had any communication with either the Individual Defendants or representatives of the FDA—fail to demonstrate that any Individual Defendant was aware, prior to February 3, 2020, that the FDA would require BD to receive comprehensive 510(k) approval prior to the continued marketing of the Alaris products. For example, Plaintiff touts the fact that there were various meetings including "managers" of certain departments at which the participants discussed the potential need for 510(k) approval. But the SAC nowhere alleges that any of the Individual Defendants were participants at these meetings or received reports of the same.[32]

To salvage these circumstantial allegations, Plaintiff claims that the assertions are "corroborated by Defendants' post-Class Period statements," which Plaintiff further argues are sufficient to find that the statements made during the Class Period were made with the requisite scienter. (Opp. at 46.) The centerpiece of this argument is that Defendants' post-Class Period references to the "ongoing dialogue" and "continuing" work with the FDA regarding a software remediation plan demonstrate that the Individual Defendants were aware during the Class Period of the purportedly concealed facts. Plaintiff also champions Defendant Polen's statement on May 7, 2020 that the "executive team is directly engaged on this on a daily and weekly basis" and

---

[32] The strength of Plaintiff's proposed inferences is further undermined by the at-times contradictory allegations made by its confidential witnesses. For example, one witness alleges that a 2016 assessment "concluded that BD needed to file a 510(k) application" (SAC ¶ 138), while another alleges that the "Regulatory Department 'came to the realization'" that BD needed 510(k) clearance, in 2019 (SAC ¶ 130). These obvious contradictions call into question the reliability of Plaintiff's witnesses. Tellabs, 551 U.S. at 320–21 (2007), ("omissions and ambiguities" in the testimony of confidential witnesses militate against inferring scienter).

that the FDA's action was "the critical priority for the company." (SAC ¶ 245.) But these statements say nothing about when the executive team became involved in this dialogue or what the Individual Defendants knew during the Class Period.

ii. *Neither the Individual Defendants' high-ranking positions nor the Core Operations Doctrine are sufficient to support an inference of scienter.*

Plaintiff also attempts to plead scienter based on Defendants' positions as high-ranking executives and the relative importance of the Alaris suite of products to the Company's financial performance.

Courts routinely reject allegations that a defendant's "position" within a company, even an important position, creates an inference of scienter. E.g., Fain v. USA Techs., Inc., 707 F. App'x 91, 96 (3d Cir. 2017); In re Advanta Corp. Sec. Litig., 180 F.3d 525, 539 (3d Cir. 1999), abrogated on other grounds, Tellabs, 551 U.S. at 308 (no scienter based upon defendants' "positions"). "Generalized imputations of knowledge do not suffice, regardless of the defendants' positions within the company." In re Advanta, 180 F.3d at 539 (citing Rosenbloom v. Adams, Scott & Conway, Inc., 552 F.2d 1336, 1338–39 (9th Cir.1977)). An exception to this rule may be found only in the rare instance where a business matter is so central to a company that a strong inference of scienter is inescapable. Id. (citing In re Ancor Communications, Inc. Sec. Litig., 22 F.Supp.2d 999 (D.Minn. 1998) (suggesting that such an exception may be found as to a contract that "was undeniably the most significant" in a company's history). Similarly, "under the core operations doctrine, misstatements and omissions made on 'core matters of central importance' to the company and its high-level executives gives rise to an inference of scienter when taken together with additional allegations connecting the executives' positions to their knowledge." In re Urban Outfitters, Inc. Sec. Litig., 103 F.Supp.3d 635, 653-654 (E.D. Pa. 2015). "[A] person's status as a corporate officer, when considered alongside other allegations, can help support an inference that

this person is familiar with the company's most important operations." Nat'l Junior Baseball League v. Pharmanet Dev. Grp. Inc., 720 F. Supp. 2d 517, 556 (D.N.J. 2010). However, "it is not automatically assumed that a corporate officer is familiar with certain facts just because these facts are important to the company's business; there must be other, individualized allegations that further suggest that the officer had knowledge of the fact in question." In re Heartland Payment Sys., Inc. Sec. Litig., 2009 WL 4798148, at *7 (D.N.J. Dec. 7, 2009).

In support of its argument, Plaintiff points to the outsized impact that Alaris had on the Company's bottom-line: BD Medical made up over half of BD's total annual revenue in 2017, 2018, and 2019 (SAC ¶ 27), and BD reported BD Medical's underlying revenue growth was "driven" by the "[MMS] unit's installation of dispensing and infusion systems." (SAC ¶ 256.) But, while the SAC demonstrates that Alaris was an important product within the MMS unit (SAC ¶ 106), itself a "key driver" of the BD Medical division (SAC ¶ 269), which in turn comprised about 50% of the Company's revenue in 2019 (SAC ¶ 27), this is not enough to impute scienter on an executive by virtue of their position.[33]

iii. *Forlenza's and Polen's respective stock trading does not support an inference of scienter.*

Stock sales can support an inference of scienter when they are "unusual in scope or timing." In re Synchronoss Techs., 2019 WL 2849933, at *15. However, the mere fact of trading during

[33] Indeed, the authorities to which Plaintiff cites for the proposition that scienter can be imputed by virtue of an executive's role involve 10b-5 violations concern matters exceptionally impactful on the businesses at issue. See Dr. Reddy's, 2019 WL 1299673, at *16 (alleging a stock drop of "over 50%" upon corrective disclosures); In re PTC Therapeutics, Inc. Sec. Litig., 2017 WL 3705801, at *16–17 (D.N.J. Aug. 28, 2017) (alleging a 61.6% drop on corrective disclosure); In re Genta, Inc. Sec. Litig., 2005 WL 2416970, at *7 (D.N.J. Sept. 30, 2005) (alleging a stock price decrease of 40% upon corrective disclosures); In re Viropharma, Inc. Sec. Litig., 2003 WL 1824914, at *9 (E.D. Pa. Apr. 7, 2003) (alleging a near-total collapse of the company's value based on executives' purportedly misleading statements); In re Honeywell Int'l Inc. Sec. Litig., 182 F. Supp. 2d 414, 427–28 (D.N.J. 2002) (alleging a decrease of over 40% on corrective disclosure); compare with SAC ¶ 235 (alleging stock drop of nearly 12%).

an alleged class period is not enough. In re Burlington Coat Factory, 114 F.3d at 1424. Whether a sale is "unusual in scope" depends on factors such as "the amount of profit made, the amount of stock traded, the portion of stockholdings sold, or the number of insiders involved." Wilson v. Bernstock, 195 F.Supp.2d 619, 635 (D.N.J. 2002) (citation omitted). Other factors relevant to the scope and timing of the sales are whether the sales were "normal and routine," and whether the profits were substantial relative to the seller's ordinary compensation. In re Burlington Coat Factory, 114 F.3d at 1423.

The fact that Defendant Forlenza made trades pursuant to a 10b5-1 plan entered into in December 2019 does not immunize those trades from impacting the scienter analysis. The critical inquiry in determining whether insider trades can impact on scienter is whether those trades were made while in possession of material, non-public information. While the use of a 10b5-1 plan is intended to serve as an affirmative defense to the showing that an individual traded while in possession of material non-public information, it is unable to immunize trades where the plan is created during the Class Period. George v. China Auto. Sys., Inc., 2012 WL 3205062, at *9 (S.D.N.Y. Aug. 8, 2012) ("[W]here . . . 10b5–1 trading plans are entered into during the class period, they are not a cognizable defense to scienter allegations."). Accordingly, trades made pursuant to the 10b5-1 trading plan that Forlenza entered into on December 16, 2019 are not entitled to the presumption that they were made without the benefit of material non-public information.[34]

[34] The SAC does not specify which of Defendant Forlenza's trades are subject to the December 2019 10b5-1 plan. In any event, the SAC does not allege that any other of the relevant trades were entered into pursuant to other 10b5-1 plans, and thus none of the trades can be considered immunized under such an agreement.

Still, even when considering all the trades during the Class Period, Plaintiff's allegations are insufficient to give rise to a strong inference of scienter. While the dollar value of the trades—combined between the two men at $58,417,985.36—is substantial, the sales comprised approximately 14% and 18% of Forlenza's and Polen's total common stock holdings, respectively, as of December 1, 2019.[35] The relative magnitude of their retained holdings rebut the inference that they had the motive to commit fraud. Compare In re Party City Sec. Litig., 147 F. Supp. 2d 282, 313-14 (D.N.J. 2001) ("Low aggregate sales and large retained aggregate holdings rebut an inference of motive, even where some defendants have sold significant percentages.") and In re Advanta, 180 F.3d at 539 (allegations insufficient to establish strong inference of scienter where defendants sold 7% and 5% of their holdings, respectively) with In re Suprema, 438 F.3d 256, 277 (3d Cir. 2006) (denying motion to dismiss where defendants sold 51% and 38% of their holdings, respectively) and In re Synchronoss Techs., 2019 WL 2849933, at *15 (denying motion to dismiss where defendant sold over 50% of the holdings).

Nor does the timing of the sales change the equation. While certainly an outsized amount of sales compared to preceding periods may indicate scienter, the handful of data points that Plaintiff provides do not give do so. According to the SAC, "Forlenza sold four times more BD common stock in the three-month Class Period than he sold during the same three-month period the year prior, and twelve times more than in the three-month period that immediately preceded the Class Period." (SAC ¶ 250.) The authorities that Plaintiff offers for the contention that these increases in Forlenza's stock sales are unusual are distinguishable insofar as they present far more dramatic increases than that here. Cf. e.g., In re Suprema, 438 F.3d at 277 (denying motion to dismiss where sales during the class period were over five times greater than all other sales

[35] Smith Decl., Ex. L.

Defendant previously made).[36] Furthermore, Defendant Forlenza's resignation vitiates the implication that these trades were made with suspicious timing. In re Synchronoss Techs., 2019 WL 2849933, at *17 ("[A]ny uptick in sales prior to Rosenberger's resignation is not particularly surprising, as such a practice is relatively common.").[37] Of course, Plaintiff's argument for the unusual nature of Defendant Polen's sales—that he sold 18% more shares during the Class Period compared to the preceding three-month period—is even weaker and must fail.

Finally, while the fact that all Individual Defendants are not alleged to have engaged in insider trading does not prohibit the Court from considering potential insider trading from certain of the Individual Defendants, see, e.g., In re Suprema, 438 F.3d at 277, it cuts against the implication that the statements were the result of a coordinated attempt to defraud the shareholders, In re Hertz, 905 F.3d at 120. At the very least, it undermines Plaintiff's argument that Defendant Reidy—who is not alleged to have conducted any trades during the Class Period—acted with scienter. Oran, 226 F.3d at 289.[38]

---

[36] The Court also notes that Forlenza was BD's CEO for nearly eight years prior to the Class Period. Limiting the trading analysis to a twelve-month period is an unnecessarily myopic recounting of his trading history and, absent a truly extraordinary discrepancy in such a brief trading history, is insufficient to demonstrate a strong inference of scienter.

[37] Plaintiff's argument that the sales were "clustered after dates on which each is alleged to have made false statements to investors" is unconvincing. (Opp. at 38.) Such an argument may be persuasive when stock sales occur prior to market-moving announcements, but here Plaintiff alleges that Defendants' statements merely maintained an artificial price. Under Plaintiff's theory, Defendants would not receive any benefit from clustering their trading at any time other than shortly prior to the corrective disclosure. Compare with In re Urban Outfitters Inc. Sec. Litig., 103 F. Supp. 3d 635, 655 (E.D. Pa. 2015) (sales one week before disappointing announcement "particularly suspicious").

[38] The Court affords minimal weight to Defendant's argument that the shares were not sold at the Class Period's highest price counter an inference of scienter. Defendants cannot be expected to predict the market with precision. Azar v. Yelp, Inc., 2018 WL 6182756, at *19 (N.D. Cal. Nov. 27, 2018).

B. Sections 20(a) and 20A Claims

Section 20(a) of the Exchange Act "creates a cause of action against individuals who exercise control over a 'controlled person,' including a corporation, that has committed a violation of § 10(b)." Avaya, 564 F.3d at 252; see also 15 U.S.C. § 78t(a). A Section 20(a) claim thus imposes secondary liability on the controlling person for the wrong committed by the one who is controlled. In re Suprema, 438 F.3d at 284–85. In this case, Plaintiff's control person claim against Forlenza, Polen and Reidy is predicated upon their primary liability of Defendant BD under Exchange Act Section 10(b). Similarly, to establish a violation under Section 20A of the Exchange Act, Plaintiff must, among other things, first identify a predication violation of the Exchange Act. See City of Edinburgh Council v. Pfizer, Inc, 754 F.3d 159, 167 (3d Cir. 2014).

Defendants correctly argue that because the SAC fails to state an actionable Section 10(b) and Rule 10b-5 violation, the Sections 20(a) and 20A claims necessarily fail to state claims upon which relief may be granted. Id. at 285; Shapiro v. UJB Financial Corp., 964 F.2d 272, 279 (3d Cir. 1992) (holding that "once all predicate § 10(b) claims are dismissed, there are no allegations upon which § 20(a) liability can be based."); In re Advanta, 180 F.3d at 541 ("[C]laims under section 20A are derivative, requiring proof of a separate underlying violation of the Exchange Act."). Accordingly, these claims will be dismissed. [39]

III. CONCLUSION

For the reasons discussed in this Opinion, the Court will grant Defendants' motion and will dismiss the SAC pursuant to Federal Rule of Civil Procedure 12(b)(6). Plaintiff hereby is granted leave to amend the complaint within 45 days of the entry of the Order to issue with this Opinion.

[39] Because Plaintiff have failed to sufficiently allege other elements of his securities fraud claims, the Court does not consider whether the SAC pleads loss causation

See Grayson v. Mayview State Hosp., 293 F.3d 103, 108 (3d Cir. 2002) (holding that upon granting a defendant's motion to dismiss a deficient complaint, a district court should grant the plaintiff leave to amend within a set period, unless amendment of the complaint would be inequitable or futile).

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

Dated: September 15, 2021